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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/812,746

03/29/2004

Jacob Guth

05408/100M675-US1

5468

7278

7590

04/28/2009

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EXAMINER

MARX, IRENE

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

04/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/812,746	Applicant(s) GUTH ET AL.	
	Examiner Irene Marx	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-23 is/are pending in the application.
- 4a) Of the above claim(s) 11-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-10, 14-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 2/12/09 has been entered.

Claims 1, 4-10, 14-23 are being considered on the merits

Claims 11-13 are withdrawn from consideration as directed to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 18 and 20-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague, indefinite and confusing in the recitation of "or a mixture thereof" at line 6 and at line 7. The mixtures intended by each of these recitations is not delineated with sufficient particularity. For example, it is unclear whether the first mixture is a mixture of enzymes or a mixture of enzymes and hydroxy acids.

Claims 18 and 22-23 are confusing in that they lack antecedent basis in claim 1 and claim 14, respectively for "a papain".

Claims 22 and 23 are vague, indefinite and confusing in the recitation of "proteolytic units (PU)" for "a papain". It is unclear what these units intended to denote in the context of the invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

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international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4, 10, 14-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Elliott *et al.* (U.S. Patent Publication No. 2003/0175232) in light of Enzyme Nomenclature (<http://www.chem.qmul.ac.uk/iubmb/enzyme/EC3/4/21/62.html>)

The claims are be directed to a topical composition comprising L-carnitine and/or an acyl L-carnitine or their salts and one or more of hydroxy acids, proteolytic enzymes, skin lightening agents as topical preparations having a pH of about 6 to about 8.

Elliott *et al.* disclose a topical composition comprising L-carnitine and one or more of proteolytic enzymes, such as the peptidase subtilisin, having a pH of about 6 to about 8 and comprising enzymes having an optimum pH of about 6 to about 7 as well as one or more hydroxy acids. See, e.g., table at page 16.

That the subtilisin used is a peptidase is adequately demonstrated by Enzyme Nomenclature.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant's bald statement that Elliott does not disclose topical compositions containing the claimed ingredients is noted. However, Elliott discloses the use of subtilisin in topical composition comprising L-carnitine. It is noted that subtilisin is a peptidase. Therefore, the invention remains properly anticipated by the reference. See, e.g., Table 16.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-10, 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elliott *et al.* (U.S. Patent Publication No. 2003/0175232) taken with Paul (U.S. Patent No.

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6,149,924), Cavazza et al. (EP 0631779), Johnsen (US patent 3,683,939), Vromen (US patent 6,416,759), Yu *et al.* (US patent 5,589,505) and Deckner *et al.* (U.S. Patent No. 5,968,528).

The claims are directed to a topical composition comprising L-carnitine and/or an acyl L-carnitine or their salts and one or more of hydroxy acids, proteolytic enzymes, skin lightening agents as topical preparations having a pH of about 6 to about 8.

Elliott *et al.* disclose a topical composition comprising L-carnitine and one or more of proteolytic enzymes, such as the peptidase subtilisin, as topical preparations having a pH of about 6 to about 8 and comprising enzymes having an optimum pH of about 6 to about 7. See, e.g., table at page 16. In addition, Paul discloses topical compositions comprising L-carnitine and a hydroxy acid. See, e.g., col. 3 and 6. Glycolic acid is a preferred hydroxy acid (col. 15, line 16).

The references differs from the invention as claimed in the presence of various other components such as papain and specific skin lightening agents.

However, Cavazza discloses the use of various additives in cosmetic compositions. See, e.g., page 8. In addition, Johnsen discloses that the pH for cosmetics is favorable in the range of 5.5 to 7 (col. 5). In addition, Vromen adequately demonstrates that proteolytic enzymes such as papain are routinely added to cosmetic or topical compositions. See, e.g., col. 2.

With regard to the use of skin bleaching agents, Yu *et al.* adequately demonstrate that it is old in the art to add various materials to cosmetic compositions, such as skin bleaches. See, e.g., col. 2. In addition, Deckner *et al.* teach the specific skin lighteners kojic acid and arbutin (col. 31, lines 40-60). This reference also discloses the use of hydroxy acids such as salicylic, glycolic and lactic in topical compositions. See, e.g., col. 31, lines 1-12. Moreover, the use of carnitine in such compositions is disclosed at col. 24, line 22. Deckner teaches that the pH should preferably between 5 to 8. (Col. 10, line 15.)

It would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the compositions of Elliott *et al.* and Paul containing L-carnitine and α -hydroxy acids and/or peptidase by using various additives to the cosmetic composition and keeping the pH at between 5.5 and 7 for example, including bleaches, lighteners, etc. as suggested by the teachings of Cavazza et al., Johnsen, Vromen, Yu et al. and Deckner *et al.* for the expected benefit of providing an efficient and mild topical composition suitable for

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rejuvenating ageing skin.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments as they pertain to the above rejection have been fully considered but they are not deemed to be persuasive.

Applicant argues that a pH of about 6 to 8 has unexpectedly improved exfoliating performance. However, as noted previously, Elliott *et al.* disclose a topical composition comprising L-carnitine and one or more of proteolytic enzymes, such as subtilisin, which is a peptidase and a suitable additive, as topical preparations having a pH of about 6 to about 8 and comprising enzymes having an optimum pH of about 6 to about 7. See, e.g., table at page 16.

Moreover, there is no clear indication of the identity of the ingredients in the touted composition which result in the effect of the composition having an unexpectedly improved exfoliating performance. In addition, the invention as claimed in the independent claim does not require the presence of an exfoliating enzyme such as papain, an enzyme that is recognized to be suitable for cosmetic preparations.

The invention as claimed requires:

(a) at least one compound selected from (i) L-carnitine, (ii) an acyl L-carnitine, (iii) a salt of L-carnitine, and (iv) a salt of an acyl L-carnitine or a mixture thereof
and

(b) **one or more of**

hydroxy acids,

proteolytic enzymes selected from papain, bromelain, pepsin, peptidase, trypsin, enterokinase, alpha-chymotrypsin,

or a mixture thereof,

skin lightening agents,

or a mixture thereof.

There is no clear requirement for a proteolytic enzyme. In addition, the nature and amount thereof are not part of the claimed invention. Thus a pH correlation with exfoliation is

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not material to the invention as claimed, since a composition comprising a specific amount of papain activity, for example, is not the claim designated invention.

Moreover, the only composition comprising papain and L-carnitine at pH 7 is disclosed at Specification [0085]-[0087]. The composition of interest contains specific amounts of L-carnitine and papain and does not appear to comprise one or more hydroxy acids or skin lightening agents the effect of which on pH and exfoliating activity cannot be assessed.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/
Primary Examiner
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